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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
07/158,652	02/22/1988	MARC ALIZON	PAST-010-A	3369

7590

02/11/2005

FINNEGAN, HENDERSON, FARABOW,
GARRETT AND DUNNER
1300 I STREET, N.W.
WASHINGTON, DC 200053315

EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 02/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

07/158,652

Applicant(s)

ALIZON ET AL.

Examiner

Jeffrey Fredman

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on December 30, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 142-151 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 142-150 is/are allowed.
- 6) ☒ Claim(s) 151 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/1/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status

1. Claims 142-151 are pending.

Claim 151 is rejected.

Claims 142-150 are allowed.

Any rejection which is not reiterated in this action is hereby withdrawn as no longer applicable.

Double Patenting

2. Claim 151 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,627,395. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Claim 1 of U.S. Patent 6,627,395 teaches a method for preparing and detecting HIV-1 RNA from a lysate of an HIV-1 virus, said method comprising:

(a) providing a biological sample that comprises human CD4+ lymphocytes infected with HIV-1 virus;

(b) separating said virus from said human CD4+ lymphocytes;

(c) centrifuging said separated virus to form a fraction comprising concentrated virus;

(d) isolating said fraction comprising concentrated virus;

(e) lysing said virus;

(f) precipitating the RNA of said virus; and

(g) detecting said viral RNA..

This claim represents a species of the current, broader generic claim in which step (a) of claim 1 of U.S. Patent 6,627,395 teaches the step of providing a biological fluid comprising HIV-1 infected cells, step (b) of claim 1 of U.S. Patent 6,627,395 teaches the step of preparing a cell free supernatant from the biological fluid, step (c)-(d) teach the step of isolating the HIV-1 virions from the cell free supernatant and steps (e) teaches the disruption of the virions to release the HIV-1 RNA. Claims 2-6 of U.S. Patent 6,627,395 demonstrate that multiple isolation methods were contemplated, supporting the broad scope of this double patenting analysis.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Allowable Subject Matter

1. Claims 142-150 are allowed.
2. The following is a statement of reasons for the indication of allowable subject matter: Claims 142-150 are drawn to specific nucleic acid sequences which comprise a region of the HIV-LTR and additional sequence. The Chang patent, cited as prior art

above, does not teach the HIV-LTR sequence with a priority date prior to that of the current application, as Applicant correctly notes. Therefore, the claims are novel and unobvious over the prior art.

Response to Arguments

3. Applicant's arguments filed December 30, 2004 have been fully considered but they are not persuasive.

Applicant argues that a prior art claim to a method of analyzing a "biological sample" would not render prima facie obvious a claim which was drawn to a "biological fluid". First, this argument is not found persuasive because the question is whether an ordinary practitioner would immediately envisage a biological fluid as a biological sample. The premier and first biological sample that would contain lymphocytes is blood. An ordinary practitioner, confronted with a claim in which a biological sample with lymphocytes is required, would interpret this as a blood sample. Second, since, in fact lymphocytes are blood cells themselves, any biological sample containing such cells would necessarily comprise biological fluid since the cells themselves have fluid and are biological in nature. So any sample with lymphocytes would necessarily comprise a "biological fluid". Therefore, the double patenting rejection is maintained.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within


Art Unit: 1637

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jeffrey Fredman
Primary Examiner
Art Unit 1637

2/9/05